K060873

ATTACHMENT 2: 510(k) SUMMARY

APR 14 2006

A.

Proprietary Name: Vanguard Breast MRI Auxiliary Table with 8 Channel Coil Array for GE Signa ™ systems.

Classification Name: Magnetic Resonance Imaging Accessory

Common Name: Vanguard Breast MRI System

Classification: Class II

Contact Person: Cameron Piron, President

Date of Preparation: Dec 31st, 2005

B.

Predicate Device:

(Model OBC-300 Breast Array Coil, MRI Devices Corp, K993776) with

(Breast Immobilization and Biopsy Device MR-Biopsy 160, MRI Devices Corp, K010570)

C.

Establishment Registration #: Applied for and Pending

Manufacture Facility Location:

Sentinelle Medical Inc.
3080 Yonge Street, Suite 6020, M4N 3N1
Toronto, Ontario, Canada
Telephone: 416-482-3828, Fax: 416-482-3807

Performance Standard:

No applicable performance standards have been issued under Section 514 of the Food, Drug and Cosmetic Act.

Indications for use:

The Sentinelle Vanguard Breast MRI Auxiliary Table with 8 Channel Coil array is designed to provide magnetic resonance images of breast anatomy when used in conjunction with a Magnetic Resonance Scanner. These images can be interpreted by a trained physician. When used with the disposable sterile plate the Sentinelle Vanguard Breast MRI Auxiliary Table with 8 Channel Coil array permits access to the breast anatomy for biopsy and localization procedures that can be performed by a trained physician.

Device Description:

The **Vanguard Breast MRI Auxiliary Table with 8 Channel Coil Array** is an MRI imaging coil and interventional system for breast. The system consists of a table base and a table top. The tabletop supports the patient, the imaging coils and means for modest compression/immobilization of the breast, as well as a means of enabling interventional device guidance. The table base is used to support and transport the tabletop. The table base is substantially equivalent to the table provided by General Electric with their GE Signa ® MRI machines.

The tabletop, like other breast coils provides an aperture to admit the breasts. A corresponding aperture in the table base maximizes physician access to the breast(s) when the tabletop is at the home position. This is useful for guidance of interventional devices (such as biopsy needles), especially when it is desired to perform a biopsy from a medial approach.

When performing a stereotactic interventional procedure (such as biopsy or wire localization), one or more compression plates may be interchanged for a sterile, single use, disposable fenestrated plates. The fenestrated plate has apertures which permit the

physician to access the breast for intervention. No biopsy needles are included with or packaged with the system.

The tabletop's receive-only coil system acts to passively collect RF emissions from the nuclei excited by the MRI. The function of the tabletop is substantially equivalent to predicate devices used for breast MRI imaging and intervention.

The Vanguard phased array coil set consists of 8 RF coil elements in a phased array design. The 8 coil array may be interchanged with a four coil array. The coil elements and associated circuitry are enclosed to prevent exposure to the patient or the environment. The coil electronics are enclosed in a rigid housing that is resistant to fluids and is fire retardant. The coils are positioned close to the patient's breast during imaging. This receive-only coil is designed to give an improved signal-to-noise ratio, image resolution and image acquisition over that of a standard body coil.

This system is for use with GE Signa ® (3X-LX, Echo Speed, TwinSpeed) 1.5T Scanners. This system is compatible with GE Signa ® Excite platforms.

Safety and Effectiveness:

Equivalency Table:

Vanguard Breast System with 8 Channel Coil Array	**Comparison to predicate device or other 510K cleared products**
Indications for Use: The Sentinelle Vanguard Breast MRI Auxiliary Table with 8 Channel Coil array is designed to provide magnetic resonance images of breast anatomy when used in conjunction with a	Same intended indications for use as K041481 - BBC-127 as indicated: **Indications for Use:** To be used in conjunction with a Magnetic resonance scanner to: 1) Product diagnostic images of the female breast, chest wall and axillary tissues that can be interpreted by a trained

Magnetic Resonance Scanner. These images can be interpreted by a trained physician. When used with the disposable sterile plate the Sentinelle Vanguard Breast MRI Auxiliary Table with 8 Channel Coil array permits access to the breast anatomy for biopsy and localization procedures that can be performed by a trained physician.	physician. 2) Permit MR-guided breast biopsy and localization of lesions that can be performed and interpreted by a trained physician. The two indications for use statements are the same in content and will be used for similar clinical indications. This does not affect substantial equivalence.
Design and Technology: The device supports a patient in a prone position, with receive-only antennas surrounding the breast. Compression plates supported by the device are used to immobilize the breast in the opening provided. Only non-ferrous materials are used in the construction of the device. Detailed aspects of technology presented in sections below.	General technology and design is the same as predicate device: K041481 - BBC-127. The major technological difference is the integration of the auxiliary table to the coil system. A more detailed comparison of similarities and differences in detailed design components are provided in Attachment 8. The sum of these presented differences does not affect substantial equivalence as discussed.
Coil Enclosure and compression plate material: Flame retardant Polycarbonate plastic and Acetal Resin.	- Acetal Resin plastic material is same as that used for coil enclosure in K013485 – Machnet. - Polycarbonate plastic material is same material as used in K041481 - BBC-127.
Technology - Coil Design: 8	- A similar coil geometry is used for the 8 coil

loop phased array receive only coil design. 1 lateral left, 1 lateral right, 1 medial left, 1 medial right coil arrays. 4 loop phased array receive only.	cardiac array (K032045). In this geometry 4 coils are formed in a linear array on two sets of coil plates. These 2 sets of coil arrays image the anatomy from different orientations. The size of the coils is different for the cardiac application as they are significantly larger. As coil geometries need to be modified to accommodate various anatomies, this difference is expected for breast imaging, and does not affect the safety of the device and does not affect substantial equivalence to the predicate. Modification of the coil geometry in such a manner does not negatively affect the safety of the proposed device and does not deviate significantly from predicated coil designs.
Technology - Decoupling: Active PIN Diode switching blocking circuitry. Passive Blocking Circuitry.	- Active PIN diode circuitry is used in K993776 OBC, and K041481 - BBC-127 which is also used in the proposed device. The circuitry is designed differently in both predicate devices however the effect is the same. All circuits act to detune the coil during a blocking signal provided from the scanner. Various blocking circuits are used in predicate devices. The particular difference does not affect substantial equivalence as they provide the same desired effect. - Passive blocking Circuitry is used in K993776 OBC, and K041481 - BBC-127 which is also used in the proposed device. The same type of circuit is used, however the capacitor and inductor values are different. This is expected at

	the coil sizes are different. This difference does not affect substantial equivalence as the same desired outcome is accomplished.
Technology - Prevention of RF Burns: Cables can not be looped.	- Reducing the likelihood of RF burns has enabled by increasing the stiffness of the cable. Cable stiffness has been increased by addition of an outer cable sheath in the predicate devices (K993776, K041481). This is the same as the proposed device by the use of an outer sheath. The material used for the outer sheath is different, but provides the same desired effect.
Technology - Radio Frequency Absorption: Coil is a receive-only coil and does not transmit RF power. Power deposition is limited by the SAR program of the MRI magnet.	- Operation is the same as (K993776, K013485, K041481).
Technology - Formation of Resonant Loop: Decoupling isolates the coil elements from RF fields during RF transmission.	- Same as K993776 – OBC, K013485 – Machnet, K041481 - BBC-127. The decoupling strategy is standard for many MRI coil systems.
Intervention: Disposable biopsy plate material – polycarbonate resin, 20 mm apertures	- Same as K041695 - Liberty 9000, K041481 – BBC-127. The similar resin and similar structure is used. BBC-127 has same aperture size. The geometric modification does not affect substantial equivalence.
Performance Testing: Performance was determined according to NEMA standards	- A comparison to the predicate device K993776 has been provided in the Verification Reports (Attachment 5) with respect to Signal

for MRI Coils.	to Noise ratio and uniformity according to these standards. Additional comparison has been made in volunteers in Attachment 9. The results conclude that the performance of the proposed device is improved relative to the predicate device and offers no additional risk with respect to safety of the device.
Specifications - Mode of operation, Frequency, Field Strength : Receive-only, 63.86 MHz Factory Set, 1.5 Telsa, 30 cm Field of View, Bilateral and unilateral applications, Medial, Lateral and anterior access.	- Same as K993776 – OBC, K041481 - BBC-127, K041695 - Liberty 9000. All operated at the same frequency, same field strength, and all all receive-only coils. Same field of view. Same unilateral and bilateral applications. Presented system has additional anterior access, while others only have lateral (OBC) and lateral/medial access (OBC, BBC). This access difference does not affect safety and does not affect substantial equivalence.
Compatibility: This system is for use with GE Signa ® (3X-LX, Echo Speed, TwinSpeed) 1.5T Scanners. This system is compatible with GE Signa ® Excite platforms.	- Same as K993776 – OBC, K041481 - BBC-127, K041695.
Table Specifications: For use with General Electric Signa ® MRI Systems. Max table weight 350 lbs. Patient table driven by GE system.	Differs only from predicate K041476 – table accessory as the table can not be raised up and down. This feature does not affect the safety and effectiveness of the presented device. All safety mechanisms on the presented device function to provide the same level of safety and functionality to the predicate device.

Testing Information and Conclusion:

There is no change to the magnet, rf system, and gradient system of the GE Signa® System by introduction of the auxiliary patient table. The receive coil system operates in a substantially equivalent manner to standard coil systems as indicated.

Operation of the GE Signa ® system with the auxiliary table is substantially equivalent to standard operation of the GE Signa ® system. The auxiliary table is docked in-place of the Signa ® system table and provides the identical docking and passive patient transfer functionalities. The functioning and safety features with the auxiliary patient table are substantially equivalent to the Signa ® system. Verification testing was performed according to internal procedures and is presented in this documentation.

Verification of imaging was performed to determine the effectiveness of the imaging system using two imaging phantoms indicative of the MRI imaging properties of a female breast. The first test compared a predicate device (K993776) signal to noise relative to the two different imaging modes of the Vanguard system. The second test used two different imaging modes of the Vanguard system (4 coil bilateral verses 4 coil unilateral) to perform a signal to noise and image uniformity comparison.

The first test demonstrated the Vanguard coil arrangements demonstrated improved signal-to-noise over that of the predicate device (K993776). The second test demonstrated the 4 coil unilateral imaging mode demonstrated improved signal-to-noise than the 4 coil bilateral mode. From these tests the Vanguard imaging modes were shown to provide signal-to-noise exceeding the predicate device.

Operation of the General Electric Signa® MRI system with the new Vanguard Breast System is substantially equivalent to standard operation of the Signa® MRI system. Additional SNR and image uniformity measurements were performed for the new imaging coil and presented in this documentation.

Use with MRI Models:

This system is for use with GE Signa ® (3X-LX, Echo Speed, TwinSpeed) 1.5T Scanners. This system is compatible with GE Signa ® Excite platforms.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 14 2006

Sentinelle Medical, Inc.
% Mr. Daniel W. Lehtonen
Responsible Third Party
Intertek Testing Services NA, Inc.
2307 East Aurora Rd., Unit B7
TWINSBURG OH 44087

Re: K060873
Trade/Device Name: Vangard Breast MRI Auxiliary Table with 8 Channel Coil Array for GE Signa™ Systems
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: March 29, 2006
Received: March 30, 2006

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060873

Device Name: Vanguard Breast MRI Auxiliary Table with 8 Channel Coil Array for GE Signa ™ systems

Indications for Use:

The Sentinelle Vanguard Breast MRI Auxiliary Table with 8 Channel Coil array is designed to provide magnetic resonance images of breast anatomy when used in conjunction with a Magnetic Resonance Scanner. These images can be interpreted by a trained physician. When used with the disposable sterile plate the Sentinelle Vanguard Breast MRI Auxiliary Table with 8 Channel Coil array permits access to the breast anatomy for biopsy and localization procedures that can be performed by a trained physician.

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060873

Prescription Use X
(Part 21 CFR 801 Subpart D)

~~AND~~/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)